EXCESSIVE DRUG PRICING IN INDIAN PHARMACEUTICAL MARKET: EXPLOITATIVE PRACTICE OR AGGRESSIVE COMPETITION CONDUCT?

Prerna Raturi

INTRODUCTION

Exploitative excessive pricing is one subject matter relating to Competition law that still remains a slippery slope. Application of excessive prices by a dominant firm is undeniably one of the most conspicuous form of abuse and thus, on the face of it, calls for regulation. However, different jurisdictions and their competition-regulating institutions are divided on this. A disagreement can be seen in their antitrust systems through their approaches and policies towards the same. Where on one hand certain jurisdictions believe that competition enforcement is not a suitable treatment for excessive pricing, others reckon excessive pricing to be well within the realm of competition law.[1] One of the most discussed and well-known examples is of American and European competition law regimes. EU competition law and judicial precedents state that excessive pricing by a dominant firm is unlawful. However, American antitrust law does not forbid the same as a form of abuse. Article 102 (a) of TFEU prohibits such conduct by a dominant company which *"directly or indirectly imposes unfair purchase or selling prices or other unfair trading conditions"*. This provision not only encompasses the imposition of extremely low prices, also called predatory pricing, but also proscribes the infliction of extremely high prices by the dominant firms. Whereas, Section 2 of the Sherman Act considers only acquiring and maintaining a monopoly by engaging in an abusive conduct a felony. That is why charging of monopoly prices in the US is not only legally permitted but also considered as an essential element of the free market system.[2]

Competition law in India is widely based on the regulatory template of the EU Competition law and borrows various provisions from it. Consequently, section 4 of the Indian Competition Act, 2002, prohibits abuse of dominant position by an enterprise or group. It defines the term "dominance" and lays down the conditions under which the unilateral behavior of a dominant

[1] F. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6(3) IRVINE L. REV. 281, 290 (2016).
[2] Verizon Communications Inc. Law Offices of Curtis v. Trinko, 540 US 398 (2004).

entity is abusive in the relevant market. An abuse of dominant position transpires when an entity impairs the competition and drives out the competitors, by virtue of its position in the relevant market. Section 4(2)(a)(ii) prohibits such conduct by a dominant company which *"directly or indirectly imposes unfair or discriminatory price in purchase or sale (including predatory price) of goods or services"*. Alike Article 102 of TFEU, abuse of dominance under Section 4 includes both predatory and excessive pricing. Competition Commission of India (CCI) plays a chief role in establishing the legal framework regulating the competition in Indian markets and thus, is also responsible for preventing the excessive pricing that impedes the entry to a particular market or distorts the competition in it. Despite this, CCI has dealt with only few cases involving excessive pricing as one of the allegations.[3] All the more so, there has not really been a specific case dealing individually with excessive pricing and that is why one cannot even find a judicial precedent guiding the firms while formulating their pricing policies.

The reason for contradicting approaches, when dealing with excessive pricing, is the conflicting beliefs of the policy makers and economists regarding the merit of competition law to be a suitable instrument for regulating the vice of excessive pricing. Interventionists are of the view that one of the objectives of the competition law is to ensure consumer welfare by limiting the exploitative behavior. Evidently enough, such an objective cannot be achieved by disallowing the addressal of excessive pricing cases under the legal standards of competition law. The earliest and a landmark case on the matter is of ***United Brands***.[4] This case made clear that excessive pricing must be determined in relation to the economic value of a product which must be determined by doing a cost-price analysis, i.e. whether the price of the product is excessively higher than the costs incurred in its production. If the price imposed turns out to be excessive then it must be found out if it is either unfair in itself or when compared with the price of similar or substitutable products. The European Court of Justice, through this case, paved a way for competition authorities to intervene in the matters of alleged excessive pricing but itself did not accept the Commission's claim that United Brands imposed excessive pricing for Chiquita Bananas in Germany, Denmark and Benelux in comparison to the prices of the bananas in Ireland. The Court judged the claim to

[3] Shri Shamsher Kataria v. Honda Siel, 2014 Comp LR 1 (CCI).
[4] United Brands Company and United Brands Continental BV v. EC Commission, (27/76) [1978] ECR 207.

be flawed on the ground of being based on a comparison of the price in other countries with that of Ireland, without even conducting an assessment of United Brands' margin of profits and cost structure in Ireland.

The Court observed that a firm is well within its rights to employ variable price for its product across countries in order to recover the costs and expenditure incurred by it, depending upon the competitive conditions in different geographical market. However, the case unfortunately left the question of how exactly to establish an excessive pricing abuse, unanswered. It was not until the case of ***Latvian Copyright Society,***[5] that this query was resolved. A pertinent query, inter alia, was raised regarding the validity of comparing the alleged high price with the prices in neighbouring as well as other Member states of EU for determining an abuse of dominant position. It was observed that there cannot be a straitjacket method to be made applicable in all the excessive pricing cases. Where in some cases cost-price analysis is the way to go, though only after assessing the cost structure of the firm in totality, others may require a comparative analysis with other countries, which also requires consideration of various factors such as fluctuation in demands, consumption habits, transportation charges, variance in the quality of the product and other economically driven factors.

Contrarily, another set of enforcers deems that there can never be an established method to find out if a price is actually excessive, for the reason that a price which is excessive in a particular region may not be so in another country, depending on the price-sensitivity of the customers of a geographical market. As a result, a dominant firm must not be punished for an offence which is found upon the touchstone of undefined and uncertain parameters. US antitrust law propounds that a firm that has attained and maintained monopoly through legal measures and practices should not be restrained from employing a price that it finds appropriate for Sherman Act is not a price-regulating statute.[6] Furthermore, these enforcers also advocate that rectifying alleged unfair pricing is against the underlying objective of enforcing an antitrust system in the first place i.e. enabling a robust yet competitive environment that can aid in optimization of allocative and productive efficiencies of the enterprises operating in the market. Unless these firms are allowed to adopt a

[5] Latvijas Autoru Apvienība v. Konkurences Padome, (177/16), ECLI:EU:C:2017:286.
[6] National Reporting Co. v. Alderson Reporting Co., 763 F.2d 1020, 1023-24 (8th Cir. 1985); U.S. v. Aluminum Co. of America, 148 F.2d 416, 430 (2d Cir. 1945).

business strategy or pricing scheme, they consider apposite, they cannot offer enhanced goods and provision of services to the consumers. Therefore, in order to encourage innovation and better research and development, incentivization is mandatory.

It is due to the presence of such conflicting theories and narratives that enforcement of competition law in cases involving excessive pricing are minimal, even in the jurisdictions where the statutes overtly proscribe the practice.

Excessive Drug Pricing Permeating Through the Pharma Sector

It was not until recently that the pharmaceutical markets across the globe saw a sequence of excessive pricing of various drugs. It is not to mention how crucial medicines are, from common and normal illnesses to life-threatening ailments. That is why even International law recognizes ***"access to essential medicines"*** as a part of right to the highest attainable standard of health i.e. the right to health.[7] Moreover, in 2015, members of the United Nations adopted 17 Sustainable Development Goals (SDGs), out of which one pertains to ensuring healthy lives and promoting well-being for all at all ages.[8] In order to achieve this goal by 2030, it is necessary that affordable medicines are made accessible to people but one would be hard pressed to advocate that this goal can be fulfilled amidst a recent spate of excessive drug pricing instances. However, drug manufacturers do not appreciate any sort of interference with their business schemes to price their medicines, as they deem fit, citing the costs they had to bear in the production of the medicines. An investment in the research and development (R&D) of the novel and innovative medicines is a financial burden on their pockets especially when they enter the market only after umpteen failed attempts to be effective. Maybe this is the reason that despite a substantial increase in such cases, it never garnered the attention it deserved. However, finally after years of taciturnity the longstanding discourse on excessive pricing of drugs has resumed.

[7] World Health Organization, *Declaration of Alma-Ata. In: International Conference on Primary Health Care* (Sept. 12, 1978), www.who.int/publications/almaata_declaration_en.pdf.
[8] U.N. Secretary-General, *High-Level Event on the Millennium Development Goals 25 September 2008: Committing to Action: Achieving the Millennium Development Goats: Background Note by the Secretary-General* (July 25, 2008), http://www.un.org/milleniumgoals/2008highlevel/pdf/commiting.pdf.

The most effective and dynamic enforcement jurisprudence regarding excessive drug pricing can be seen in the UK. One of the earliest cases is the ***Napp case*** where the Office of Fair Trading (OFT) alleged that Napp is pricing its off-patent painkiller morphine excessively high, especially for its sale to the public at large.[9] The OFT found the abuse of excessive pricing after conducting a two-stage test. It conducted a comparison of both, the price of morphine and the profit on its sales with the price charged and profit earned on the sales of morphine by Napp and other competitors in different markets.[10] It was learnt that the prices charged by Napp, for the sales of morphine to the public, were not only 10 times higher than the prices it imposed for the export of morphine and its sales to the hospital,[11] but also approximately 33% to 67% higher than what were being charged by its competitors.[12] Accordingly, a fine of £3.2 million (later reduced to £2.2 million by the Competition Appellate Tribunal (CAT),[13] was imposed on Napp.[14] Another vital decision on the matter came from the Italian Competition Authority (AGCM) in the famous ***Aspen Case*** in 2016.[15] Aspen had bought the trademark and marketing rights of four off-patent drugs, known as Cosmos, used for the treatment of leukemia specifically in children and old people. Cosmos drugs were reimbursed by the Italian health service and their prices were subject to negotiations with the Italian Regulator, AIFA. In 2013 Aspen mentioned its desire to AIFA to categorize the drugs as non-reimbursable so that their prices could be increased or else Aspen would withdraw the drugs from the market. Knowing the life-saving characteristic of the drugs and the absence of substitutable drugs, AIFA had to agree. When AGCM looked into the rationality of the price hike, it adopted the test established in the United Brands' case. It was assessed that Aspen was already having enough profits from the sales of Cosmos drugs but after an increase of around 1500% in the prices,[16] the profits earned ranged from 100–150% to 350–400%.[17] The prices were also determined to be unfair as neither did any non-cost factors invited an increment

[9] Napp Pharmaceuticals Holdings Ltd. v. The Director General of Fair Trading, CAT [2002] EWCA Civ 796, par. 142.
[10] *Id.,* at 203.
[11] *Id.,* at 207.
[12] *Id.,* at 215.
[13] *Id.,* at 538.
[14] *Id.,* at 264.
[15] Italian Competition Authority (AutoritA Garante del Mercato e della Concorrenza), Case A480—Price Increase of Aspen's Drugs (Incremento Prezzo Farmaci Aspen) [2016].
[16] *Id.,* at 3.
[17] *Id.,* at 184.

in the prices nor was there a qualitative improvement to the drugs. As a result, a fine of €5.2 million was imposed on Aspen for abusing its dominant position.[18] This case created a domino effect, inducing other European nations and finally, the European Commission to initiate a formal investigation against Aspen's unjustified excessive pricing of various pharmaceutical products in the entire European economic area, making it European Commission's first ever investigation into excessive pricing practices in the pharmaceutical industry.[19]

Furthermore, in 2013, the Competition and Markets Authority (CMA) of the UK (erstwhile OFT), initiated three different investigations into the excessive drug pricing cases, involving some of the biggest pharma giants.[20] Out of these three investigations, one that has already been decided upon is well known as ***Pfizer/ Flynn Pharma Case***.[21] The case dealt with phenytoin sodium capsules; a drug used for the treatment of epilepsy, originally manufactured by Pfizer in 1908 and sold under the brand name of Epatunin. The controversy regarding it arose when in 2012 Pfizer entered into an agreement to transfer the drug's marketing authorization in UK i.e. the right to sell the drug, to Flynn. As a result, Pfizer continued to manufactures the drug but Flynn became its leading distributor in UK. However, the fundamental objective behind the agreement was to first debrand the drug from Epatunin to a generic drug and then rebrand it again, once Flynn becomes the distributor. Consequently, the drug was not regulated under the National Health Service's (NHS) Pharmaceutical Price Regulation Scheme anymore, giving an opportunity to increase the price of the capsules. This sudden and substantial increase in the price caused NHS to annually expend from £2 million to approximately £50 million in 2013, £42 million in 2014 and £37 million in 2015 on the drug.[22] The CMA employed the test devised in United Brands by evaluating the costs incurred in synthesizing the drug and determining the reasonable rate of return or profit margin. Driven by the AGCM's approach in the famous ***Aspen Case***, the CMA decided a return of 6% on

[18] *Id.,* at 189.
[19] Elisabetta M. Lanza and Paola R. Sfasciotti, *Excessive Price Abuses: The Italian Aspen Case*, 9 J. EUR. COMP. L. & PRAC 382, 390 (2017).
[20] Competition and Markets Authority, *Drug Company Accused of Abusing its Position to Overcharge the NHS*, GOV.UK (Nov. 21, 2017), www.gov.uk/government/news/drug-company-accused-of-abusing-its-position-to-overcharge-the-nhs.
[21] UK Consumer and Market Authority (CMA), Case CE/9742-13, Pfizer/Flynn Pharma [2016], at 1.3-1.5. (hereinafter "UK CONSUMER CASE")
[22] *Id.,* at 5.398.

the sales of the drug to be reasonable. It was found out that Pfizer was charging a price which was 29% to 700% higher than the costs incurred and the price imposed by Flynn exceeded the costs by 31% to 133% which were way above than the agreed reasonable profit margin.[23]

After observing that the prices by Flynn and Pfizer were marred with the abuse of excessive pricing, the CMA went to decide if the prices were also unfair. It is usually argued that high prices of the medicines can be attributed to the recovery of the expenditure incurred in the development of the drug and its frequent failure to be effective before it can enter the market. But in the present case, since the drug was off patent at the time of investigation, drug manufacturers have had enough time to recover their R&D costs.[24] Therefore, in such a situation, when the patent exclusivity of the drug has expired, without any further innovation and additional development in the drug, Pfizer and Flynn are not justified in imposing extensively high and unfair prices. Subsequently, the CMA levied a fine of £84.2 on Pfizer and a fine of £5.2 on Flynn. However, on an appeal, the CAT annulled this decision stating that the CMA has adopted wrong methods to reach its finding.[25] The CAT opined that there cannot be a single method or approach to conclude that a price is excessive and thus, downright disregarded the decision of considering the price of Epatunin excessive as the CMA did not even determine a benchmark price to compare it with.[26] Furthermore, the CAT believed that the unfairness of the price was also found without sufficient comparison, especially with the prices both imposed in other countries and of other similar and comparable products.[27] Even though, the CAT explicitly stated the uncertainty and difficulty in placing an excessive drug pricing case under the competition law realm, it also made clear that it is untrue that no abuse can be found in this case, but only with correct approach, satisfying comparisons and substantial evidences. But a question that is worth asking is that how can unjustified and unfair pricing of the medicines not be condemned? What is the use of innovating and developing effective pharmaceutical drugs when they cannot even be accessed by the people in need, often to survive? While incentivizing the drug manufacturers and insulating them from antitrust scrutiny, who will ensure that the consumers interests are also protected? If despite being

[23] *Id.,* at 4.224.
[24] *Id.,* at 1.16, 3.23 and 5.268.
[25] Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v. Competition and Markets Authority, [2018] CAT 11.
[26] *Id.,* at 310.
[27] *Id.,* at 379.

delimited with the difficulty of establishing when pricing is truly excessive, European competition regulators are willing to recalibrate their standards and resolve the issue of excessive drug pricing, why cannot other jurisdictions be impelled to do the same?

In context of Indian pharmaceutical space, there is an absence of enforcement actions by the CCI against excessive pricing of drugs. There is not even a single case in which CCI has found the contravention of Section 4(2)(a)(ii) in respect of the pharmaceutical sector, despite several allegations alluding the same. One of the most known cases is of the ***Roche case***.[28] Drug makers Biocon and Mylan Pharmaceuticals complained to the CCI that the conduct of Hoffmann-La Roche AG and its group entities Genentech and Roche Products (India) Pvt Ltd. has violated various provisions of the Competition Act, 2002 amongst which one involved flouting of Section 4(2)(a)(ii). It was alleged that Roche's breast cancer treating drugs, based on Trastuzumab, were excessively priced when compared to the price of their biosimilars.[29] Even though the Commission found the conduct of Roche and its subsidiaries to be abusive, it was not convinced that they were indulged in unfair pricing since *"Roche Group being the innovator, it might have invested huge sums on research and development of Trastuzumab. Thus, initial high prices can be attributable to being the reward for innovation."*[30] It is pertinent to note that Roche registered its patent for the its drug Trastuzumab, sold under the brand name Herceptin on 5th April, 2007 but later, in 2013, abandoned it because of which the patent lapsed.[31] Later, Roche withdrew Herceptin from the Indian market and introduced a lower cost version of Trastuzumab (biosimilars), known as Biceltis and Herclon.[32] This clearly came as an anticipatory and calculative strike by Roche to avoid Indian Government's spree of issuing compulsory licensing for various blockbuster cancer-treating drugs for their extravagant prices were making them inaccessible to Indian population.[33] Furthermore, it was due to the absence of any biosimilars of Trastuzumab in Indian pharma-market that such an

[28] Biocon Limited and Mylan Pharmaceutical Private Ltd. v. F. Hoffmann-La Roche AG & Others, Case No. 68 of 2016, available at http://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf.
[29] *Id.*, at 37.
[30] *Id.*, at 80.
[31] *Id.*, at 7.
[32] *Id.*, at 8.
[33] *Roche abandons Herceptin patent in India*, GABI Online (Oct. 30, 2013), http://www.gabionline.net/Biosimilars/News/Roche-abandons-Herceptin-patent-in-India.

issuance was delayed in respect of Herceptin.[34] Thus, it was a lucrative opportunity for the Roche group to make their biosimilars enter the market. The main reason that biosimilars enter a market is to commence the inter-brand competition in otherwise monopolist market.[35] Thus, when Roche had abandoned its patent and introduced its biosimilars, there exists no reason to earn an award for innovation by charging excessive prices because neither did the biosimilars had any further innovation or additional development in them nor were they protected by virtue of a patent exclusivity. However, the Commission failed to notice this development. It instantly rejected the allegation of excessive pricing without even delving into the issue or making suitable comparisons, merely on the worn-out and trite claim of R&D and innovation costs.

Thus, the nebulous position of excessive pricing in Indian competition law brings to the light a significant query that whether it is time to develop enforcement jurisprudence on excessive drug pricing as an abuse under Competition law and regulate high prices for procurement of affordable medicines.

Viability of Proscribing Excessive Drug Pricing Through Competition Enforcement

There exist several contentions that argue that excessive drug pricing must not be rendered as an antitrust violation as it is not only overreaching for Competition regulators to intervene in such cases but also difficult to attain desired results i.e. lower drug prices. In this section, the author has tried to debunk all such frequently raised arguments.

1. Diminishing R&D Investment and Chilling Innovation: One of the fundamental reasons that non-interventionist induce Competition regulators to abstain from intervening and employing competition law to prevent the excessive pricing of drugs is that they believe and argue that it would not only limit a firm's freedom to decide the prices for their drugs but would also shrink the innovation and investment for the development of enhances and better drugs. Indeed, the costs of the drugs are set in a manner that maximum profits can be earned from their sales to recuperate the expenditure incurred by the drug makers. Thus, excessive pricing of the drugs must be

[34] *India issues more compulsory licenses*, GABI Online (Jan. 24, 2013), http://www.gabionline.net/Policies-Legislation/India-issues-more-compulsory-licences.
[35] J. Reid and M. Balasegaram, *Research & development in the dark: what does it take to make one medicine? And what could it take?*, 22 CLINICAL MICROBIOLOGY & INFECTION 655, 657 (2016).

attributed to the risk involved in spurring innovation and considered as an incentive to the drug makers.[36] However, such a belief does not hold water, especially in the case of an off-patent drug. When a drug becomes off-patent, the patent exclusivity attached with it expires. In such a case, the original drug manufacturer cannot use the defence of "chilling innovation and earning the reward for R&D investment" for he has had sufficient time and opportunity, while the patent had not lapsed, to recover the costs incurred in the drug's production. The drug is off-patent, so there exists no distress of disincentivizing. Further, one cannot even derive any pro-competitive benefits from such an increment in the price. The only justification that can be forwarded is that since the firm is a dominant entity in the market, it had the privilege to set a price it thought suitable and profiting and thus, it did. Apart from that, any defense of "incentives for innovation" is not an issue in those cases where it is raised by a manufacturer who is not the innovator of the drug.

It is pertinent to note that Section 3 of the Competition Act, 2002 prohibits the concerted agreements that cause or are likely to cause an appreciable adverse effect on competition. Despite being a provision of general application i.e. applicable to all sectors and all economic activities, an exception has been extended to Section 3. Section 3(5)(i) of the Act allows an IP holder to impose reasonable conditions, that are necessary for protecting any IP rights conferred on him. The said IP rights also includes the rights conferred to a patent holder under Patents Act, 1970. But this exception is with respect to the provision of anti-competitive agreements. Such an exemption was not extended to the cases of abuse of dominance until recently. On 12th February, 2020 the Ministry of Corporate Affairs introduced the ***Competition (Amendment) Bill, 2020***.[37] One of the provisions of the bill and the one which is relevant in the present case is that the same defence is now extended even in the cases of abuse of dominance. This suggests that while establishing a case of abuse of dominance, the rights of a patent holder (the dominant firm) will be duly recognized. Only those unilaterally adopted practices will be penalized by the Commission

[36] Akman, P. and L. Garrod, *When are Excessive Prices Unfair?*, 7(2) J. COMP L & ECON 403, 420 (2011).

[37] Competition Commission of India, *Competition (Amendment) Bill, 2020*, available at http://feedapp.mca.gov.in/pdf/Draft-Competition-Amendment-Bill-2020.pdf. (hereinafter "2020 COMPETITION BILL")

that impose unreasonable conditions in exercise of IP-protected rights and impair the otherwise undistorted competition.

2. Ephemeral Nature of Excessive Pricing and Self-Correction of Market:

One argument for not intruding in a firm's pricing behavior and strategies is that usually any excessive pricing is temporary in nature because in the presence of vigorous competition, a market self-corrects itself.[38] The more competitive the market, the lesser the chances of distorting the competition by employing the excessive pricing because the customers will shift to the other competitors.[39] If customers shift, the firm will itself alter or change its practice or scheme of excessive pricing as it will lose customers.[40] That is why it is temporal in nature in a competitive market. Reflecting this, it would mean that the presence of substitutes is necessary for customers to shift to other drugs or brands. Consequently, it is a factor which would help to determine whether the case is of excessive pricing. However, this whole argument is based on the assumption that substitutable products, in this case drugs, are always present in the market, which is not the case always. If the substitutes are unavailable or absent in the market, the firm imposing excessive pricing would not lose customers. The higher the degree of market power, the less likely it is that the market will self-correct within a relevant timeframe.[41] Furthermore, the delineation of relevant market narrows down in the absence of substitutes, establishing the excessive price imposing firm as a dominant entity in the market. Broader relevant market definition means lesser likelihood of dominance in the market. It is pertinent to not that excessive pricing is considered as an antitrust violation only when employed by dominant firms, firms otherwise are allowed to mark their products as they wish. This means that the market power of the firm is such that its pricing scheme is capable of not only affecting the competition in the relevant market but the interests of the

[38] D. Evans and J. Padilla, *Excessive Prices: Using Economics to Define Administrable Legal Rules*, 1(1) J COMP. L & ECON 97, 102 (2005).
[39] Hou Liyang, *Excessive Prices within EU Competition Law*, 7(1) EUR. COMP. J. 47, 69 (2011).
[40] A. Sarpatwari, J. Avorn and A.S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, 4 N. ENG. J. MED. 2301, 2304 (2016).
[41] Organization for Economic Cooperation and Development, *Directorate for Financial and Enterprise Affairs Competition Committee's Comment on Excessive Prices*, DAF/COMP(2011)18 (Feb. 7, 2011), https://www.oecd.org/competition/abuse/49604207.pdf.

consumers as well. Therefore, had the substitutes been available, the firm would not have been a dominant entity leaving no reason or opportunity to regulate the pricing.

Another assumption on which this argument is based is that in the presence of substitutes the consumers tend to shift to or choose other drugs or brands. This argument completely negates the fact that consumers (who are also patients) do not make a voluntary decision while buying a medicine for their ailment. Their choices are induced by the instructions provided to them by their medics and physicians.[42] These prescriptions by the doctors are not based on the prices of the medicines but their availability and more importantly, the suitability and thus, consumers cannot switch to another medication or even to another brand of the same medication. For instance, in Pfizer/ Flynn Pharma Case the fundamental reason that patients did not switch to other epilepsy medications, despite exorbitantly high prices of phenytoin sodium capsules, is that a change in medication could have triggered severe effects of epilepsy and thus, discontinuation of the capsules would have been inappropriate for the benefits of patients.[43] Therefore, in such a situation when the life of a person is at stake, will one look for a cheaper medicine or resort to the one that is prescribed and readily available, irrespective of its unashamedly high prices. Thus, it would be wrong to assume that mere presence of substitutes, if any, would make the consumers shift to them in a setting of excessive pricing of the prescribed drug.

3. Excessive Pricing Initiates Inter-Brand Competition

Another caveat for allowing the addressal of excessive drug pricing as an antitrust violation is the belief that excessive pricing of the medicines in the market attract new entries and thus, initiates inter-brand competition.[44] It is a general presumption that high prices of the products in the market usually bolsters other competitors (generics and biosimilars) to enter the market. The reason for the same is that the price of a product is directly proportional to the profits earned form the sales

[42] Charles L. Denison and Max E. Greenberg, *Excessive Drug Pricing as an Antitrust Violation*, 82 ANTITRUST L. J. 701, 713 (2019).
[43] UK CONSUMER CASE, *supra* note 21, at 3.28-3.42, 7.70; Unfair Pricing in Respect of the Supply of Phenytoin Sodium Capsules in the UK, Decision of the CMA CE/9742-13, § 1.5 (Dec. 7, 2016) (Pfizer), www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products#non-confidential-infringement-decision.
[44] Motta M. and De Streel A., *Excessive Pricing in Competition Law: Never say Never? - The Pros and Cons of High Prices*, SWEDISH COMPETITION AUTHORITY (2007), http://www.crid.be/pdf/public/7425.pdf.

of the goods, thus, high prices brings excessive profits.[45] This whole mechanism draws new entrants in the market. Therefore, in a situation when there exist no barriers to the entry and new entrants are also entering the market, an intervention from the side of Competition regulators is unnecessary and unwarranted. In lieu of regulating the prices in the market, stringent price regulation might just deter the new entrants and prolong the dominance of already dominant enterprise.[46]

The fundamental issue with this view is that it constructs on the assumption that various generics and biosimilars will enter the market on noticing high prices of the drugs. Another assumption is that their entry will cause the prices to fall and eventually make the drugs affordable. More importantly, the assumption on which all the remaining assumptions rely is that the new entrants will have no barriers to their entry in the market. In order to detest this view and the assumptions on which it is built, it is necessary to reconsider the cases already discussed above. In all the cases, *Napp*, *Pfizer* and *Aspen*, contrary to what is usually assumed, high prices of the drugs did not allure entries in the market. There was a sudden and substantial spike in the prices of the respective drugs, without any justification except for the unscrupulous desire of the firms to make their business more lucrative. Despite this, no new entry occurred in the market. There can be several reasons for the same, such as, smaller market, high capital-intensive character of the pharmaceutical industry, consumers' unwillingness to shift to other medicines or brand (which by the way, is not their personal choice but due to the prescriptions and advice of the doctors and hospitals), entry-deterrence pricing strategy, etc. These cases exhibit a crucial example of why intervention is essential and discredit the entire contention of high prices alluring new entries.

4. Institutional Difficulty in Determining a Case of Excessive Price: Enforcers' decision for non-condemnation of excessive drug pricing is also founded on the difficulty faced while determining what exactly falls squarely under the abuse of excessive pricing. Evaluating a reasonable price for a particular drug and on the basis of the same establishing a case of excessive pricing, is not only difficult but also goes beyond the competence of Competition regulators.[47] Stating that the

[45] Jenny F., *Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment*, EXCESSIVE PRICING AND COMPETITION LAW (2018), http://www.msm.nl.
[46] Fletcher A. and A. Jardine, *Towards an appropriate policy for excessive pricing*, EUROPEAN COMPETITION LAW ANNUAL (2006), http://www.competitioneconomics.org/dyn/files/basic_items/295- file/AmeliaFletcher_plenary.pdf.
[47] United States v. Addyston Pipe & Steel Co., 85 F. 271, 283-284 (6th Cir. 1898).

reasonable price of a drug would mean its actual economic value cannot be a reason enough for antitrust agencies to intervene for this argument, in itself, is intricate. The difficulty posed by the question of reasonable price of a drug would be the same even in the case of economic value of a product.[48] Further, even if a consensus is reached on what constitutes a reasonable price, how would one determine if the actual price imposed is excessive?[49] One cannot really devise a method or standard to ascertain if the margin between the reasonable price (if determined) and the imposed price is higher than what must be achieved because if the consumers are willing to pay, how can a third non-related party decide for them?[50] However, this is not a correct approach to address this issue. Consumer's willingness is not an appropriate benchmark to determine if a price is reasonable. As already stated, a consumer would anyway not be reluctant to purchase a high-priced medicine when his or his family's life is in the peril.[51] Thus, even if they are forced to pay an extensive price for a medicine, they would, even if it is not worth the money. Going by this approach, any price imposed would never be an excessive price for the consumers will still buy the essential drugs and a dominant entity would never want to fix a price lesser than what consumers are willing to pay.

Coming to the challenges faced while evaluating a reasonable price and consequently establishing a case of excessive pricing, it must be realized that a straitjacket method cannot be devised. Complex problem of excessive drug pricing cannot be solved with a simple assessment criterion. It is necessary to comprehend that several usable and comparable measures and methodologies must be employed to find out the difference between excessive pricing and lawful pricing. With respect to this, a reference of guiding opinion of Advocate General Wahl (EU Court of Justice) must be made. While deciding the *Latvian Copyright Society's* case, Advocate General Wahl was

[48] Calcagno C. and M. Walker, *Excessive Pricing: Towards Clarity and Coherence*, 6(4) J. COMP. L. & ECON. 891, 905 (2010).
[49] Berndt E., R. Conti and S. Murphy, *The generic drug user fee amendments: an economic perspective*, 5(1) J. L. BIO. SCI. 103, 137 (2018).
[50] 2020 COMPETITION BILL, *supra* note 37, at 105.
[51] David Gilo, *A Coherent Approach to the Antitrust Prohibition of Excessive Pricing by Dominant Firms*, 4 J. COMP. L. ENF'T 113, 120 (2018).

requested to provide his opinion on under what conditions a price could be labeled as excessive.[52] It was opined that in such cases a case-specific analysis must be done. A comparative analysis can surely aid in reaching to a finding. This would include *"comparison of the prices charged by the dominant company for the same product in other geographic markets, a comparison with prices that rivals charge in other markets and a comparison of prices charged by the dominant company over time if there are no good explanations for price increases."*[53] He recommended combining several methods among those which are accepted by standard economic thinking and which appear suitable and available in the specific situation". When applied with rigour and objectivity, any convergence of results from the different tests may be taken as an indicator of a reasonable benchmark price. Therefore, while acknowledging the hardships accompanied with an excessive drug pricing case, one still cannot refute that it cannot be successfully addressed and resolved.

Moreover, this not the first time that a challenge like this is posed before the Commission. For example, predatory pricing is considered as an exclusionary abuse under the Competition Act, 2002. There exist economic theories, in regards of predatory pricing as well, that proposes that regulation of predatory pricing through Competition law is not very effective. It is advocated that predatory pricing is employed in two stages. Firstly, when the price is imposed, eliminating the competitors out of the market and later, when the competitors are not in the market anymore, the dominant firm increments the price again to recover the losses it suffered in the first stage. Such an increase in the price brings back the market in its original competitive environment as competitors re-enter the market. Thus, predatory behavior of a dominant firm must also be rendered temporary. However, despite this existing belief, the CCI has not sheared from evaluating predation in the cases presented before it. A classic case of predation is the ***NSE Case***,[54] where the CCI reprimanded the NSE for indulging in predatory pricing by offering waiver in transaction fee, in respect of all currency future trades executed on its platform, and imposed a penalty of Rs. 55

[52] *The EU Court of Justice AG Wahl Offers Guidance on the Criteria to Identify Excessive Prices in Abuse of Dominance Case (AKKA/LAA*), CONCURRENCES (Apr. 6, 2017), https://www.concurrences.com/en/bulletin/news-issues/april-2017/the-eu-court-of-justice-advocate-general-wahl-offers-guidance-on-the-criteria-en.

[53] EU Court of Justice AG Wahl, AKKA / LAA, Case C-177/16 (Apr. 6, 2017), http://curia.europa.eu/juris/document/document.jsf?text=&docid=189662&doclang=EN.

[54] MCX Stock Exchange Ltd. v. National Stock Exchange of India, Case 13 of 2009, available at http://www.cci.gov.in/sites/default/files/MCXMainOrder240611_0.pdf.

crores. When an indictment of predatory pricing can be remedied by the Commission then why can the same be done in a case of excessive drug pricing?

Conclusion

Indeed, remedying a wrong like excessive drug pricing is not simple considering the underlying institutional problems and peculiar characteristics of the pharmaceutical sector but it is not obligatory that a competition regulating authority works alone towards this. Sectoral regulation of the industries is an effective way to assist the antitrust agencies. Nobody is asking the competition authorities to be the price regulator. This function can be exercised by the specific sectoral regulators. In India, the ceiling price of the essential drugs are regulated and determined through the Drug Price Control Orders (DPCOs) of Ministry of Chemicals and Fertilizers.[55] Apart from that the National Pharmaceutical Pricing Authority (NPPA) monitors the prices of the scheduled drugs and ensures their enforcement.[56] Price of the drugs which are not scheduled in the DPCO are also regulated by NPPA and must not be more than 10% per cent of the maximum retail price of the drug during the preceding twelve months.[57] In such a case where there exist a sectoral regulator, the job of the Commission gets easier, given that a sectoral regulator is at a better footing in regards of the understanding of the peculiar characteristic of their sector and possesses significant market knowledge. Due to its deeper insight of the sector and technical expertise, it is capable of assessing the appropriate price for its sectoral market and regulate the price ceiling. In respect of the decided price range, it becomes easier to figure out the cases laden with the vice of unfair pricing. Intervention at this stage would be appropriate for the CCI to create an enabling environment for the competition in the market. Other than this, the pharmaceutical companies must be obligated to be more transparent about their cost-structure. The CCI, as per its advocacy mandate in October 2018, issued a policy note titled ***"Making Markets Work for Affordable Healthcare"*** that addresses the lack of transparency and regulation of the pharmaceutical sector

[55] The Essential Commodities Act, 1955, §3, No. 10, Acts of Parliament, 1955 (India).
[56] Government of India; Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Resolution No 159 No 33/7197-P11 (Aug. 19, 1997), http://www.nppaindia.nic.in/wp-content/uploads/2019/07/PMRU-Guidelines.pdf.
[57] Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals, Drug (Prices Control) Order 2013 (May 15, 2013), https://pharmaceuticals.gov.in/sites/default/files/dpco2013gaz.pdf.

and urges the pharmaceutical enterprises to be more transparent about their R&D costs.[58] Appropriate information and knowledge regarding the cost structure would make the whole procedure of assessing an excessive pricing case more feasible.

Competition law condemns the abusive practices by a dominant firm and purports to check its conduct to preserve competition in the market. But when similar situation of distorted competition is created through unfair pricing of drugs, why cannot the CCI intervene? The Commission has not even tried to evaluate such a case on its merits, let alone remedying one. This failure of the Commission can be attributed to its narrow view of the scope of the Competition Act, 2002 and thus, is making the Indian competition law regime a safe harbor for the pricing practices of the dominant firms in pharmaceutical space. The issue of excessive drug pricing is not similar to the excessive pricing of any other goods or provision of services. Unlike the market conditions of other sectors, in the pharmaceutical space the competition in the market and the purchase of the product (drugs) is not driven by the consumer's preferences. It is not the patient who take an informed decision of buying a cheaper medicine over an expensive one, based on his price sensitivity, but the prescription of the doctors and hospitals that influences the patient's (consumer's) choices. Unlike other sectors, buyers do not have a bargaining power. Neither do they have a control on the choices they make no do they have an opportunity of resorting to better options. Therefore, it is necessary that one not only approaches this issue from a competition enabling perspective but also with an intention to ensure consumer welfare. Competition law might not only be about consumer welfare but it does tend to achieve it as one of its objectives. Thus, any divergence from the same either through excessive intervention or through excessive clemency is bewildering, considering how critical pharmaceutical sector is to the consumers. India is a country with socialist goals. That is why even the preamble of the Competition Act, 2002 mandates that the provisions of the Act must protect the interests of the consumers. Such an objective emboldens an approach that treats excessive drug pricing as an exploitative practice and necessitates the prescription of remedies for the same.

[58] Competition Commission of India, Policy Note on Making Markets Work for Affordable Healthcare (Nov. 1, 2018), https://www.cci.gov.in/node/4184.